

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

9987 '01 NOV 27 AM 11:30

Antiviral Drugs Advisory Committee; Notice of Meeting

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AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

Display Date	11-27-01 @ 11:15 am
Publication Date	11-29-01
Certifier	R. LEDESMA

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Antiviral Drugs Advisory Committee.

General Function of the Meeting: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on December 12, 2001, from 8:15 a.m. to 5:15 p.m.

Location: Holiday Inn, Versailles Ballroom, 8120 Wisconsin Ave., Bethesda, MD.

Contact: Tara P. Turner, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, e-mail: TurnerT@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12531. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will be updated on the approval of biologics license application supplement 103949/5002, PEG-INTRON (peginterferon alfa-2b) powder for injection, Schering Corp., indicated for use alone or in combination with Rebetol (ribavirin, USP), for the treatment of chronic hepatitis C in patients with compensated liver disease who have not been previously treated with interferon alpha and are at least 18 years of age.

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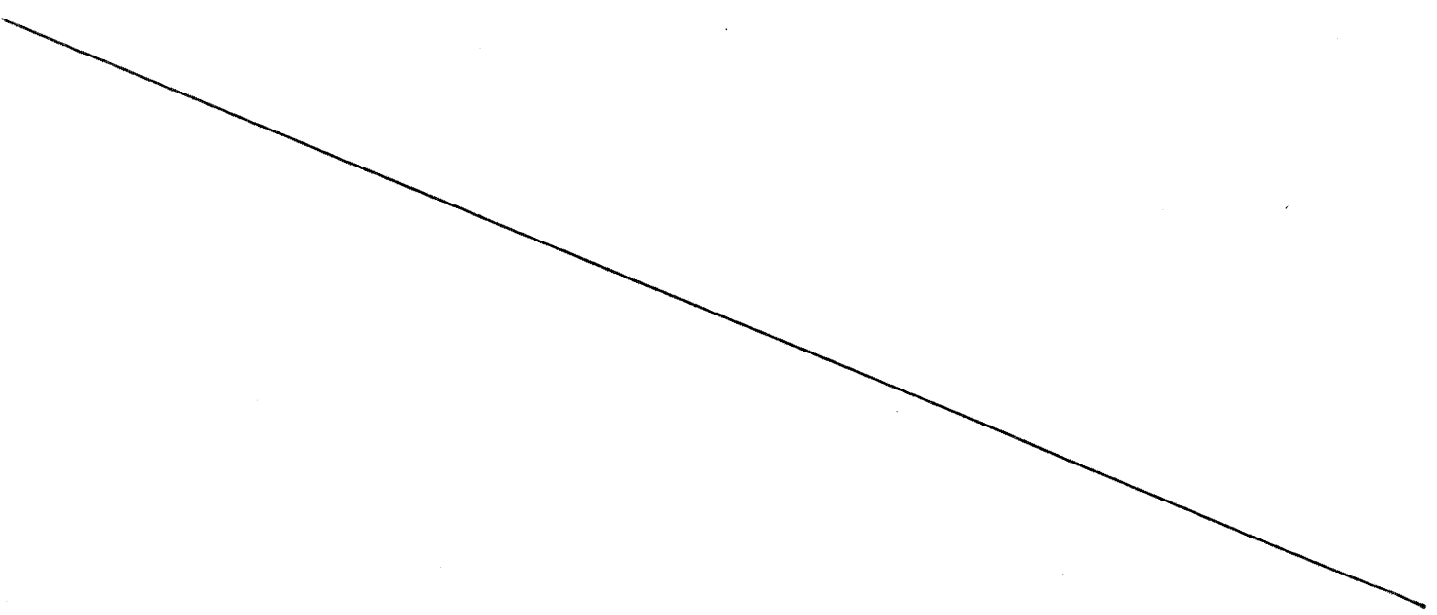
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Procedure: On December 12, 2001, from 8:15 a.m. to 12:15 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by December 5, 2001. Oral presentations from the public will be scheduled between approximately 10 a.m. and 11 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before December 5, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On December 12, 2001, from 1:15 p.m. to 5:15 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)).

FDA regrets that it was unable to publish this notice 15 days prior to the December 12, 2001, Antiviral Drugs Advisory Committee meeting. Because the agency believes there is some urgency to bring this issue to public discussion and qualified members of the Antiviral Drugs Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.



Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.

2).

Dated: Nov 21, 2001

November 21, 2001.

Bonnie H. Malkin

Bonnie H. Malkin,
Acting Senior Associate Commissioner for Communications and Constituent Relations.

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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Regina Sedesma